ICD

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/268,437	03/12/1999	YING DING	UOC/134A	8426

26875 7590 08/05/2004

WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/268,437	DING ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/2/04 has been entered.

Amendment Entry

2. Applicant's amendment and response filed 2/2/04 is acknowledged and has been entered. Claims 1 and 11 have been amended. Claim 12 has been added. Accordingly, claims 1-5, 11, and 12 are pending and are under examination.

Rejections Withdrawn

3. In light of Applicant's amendment and arguments, the rejection of claims 1-5 under 35 U.S.C. 102(b) as being anticipated by Cozzette et al. (US 5,063,081) is hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5, 11, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in reciting, "adapted to", first and second occurrences, because it is unclear how the "cell" and the "plurality of working electrodes" are modified to perform their intended function, i.e. "to hold a sample" and "to quantitatively measure enzymatic reaction product", respectively.

Claim 11 is vague and indefinite in reciting, "adapted to", because it is unclear how the "cell" is modified to perform its intended function, i.e. "to hold a sample".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-5, 11, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Henkens et al. (US 6,391,558) for reasons of record.

Henkens et al. disclose a simultaneous electrochemical assay device (biosensor array device) comprising a cell (circuit board) for holding a sample, having a plurality of plurality of working electrodes and reference, i.e. auxiliary, electrodes. Each of the working electrodes is adjacent, i.e. linked or attached to, an analyte binding area which has an analyte binding substrate and separate from other analyte binding areas by a distance (surface area). Henkens et al. teach that whether in an array of working electrodes or a single working electrode, the biosensor may optionally include one, i.e. common, or more reference counter electrodes (see column 6, lines 32-38). Analyte binding substrates (bioreporter molecules) comprise of different analyte specific proteins such as antigens, antibodies, and enzymes (reductases, peroxidases, phosphatases). See column 4, line 41 to column 6, line 38 and column 19, line 58 to column 20, line 56. The plurality of working electrodes quantitatively measure enzymatic reaction product. See column 17, line 51 to column 18, line 63 and column 41, lines 31-38. The device does not include a means to mix the sample in the cell.

6. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Cozzette et al. (US 5,063,081) for reasons of record.

Cozzette et al. disclose a simultaneous electrochemical assay device (amperometric base sensor) fabricated on a substantially planar silicon substrate comprising a unit cell for holding a sample, having a plurality of working (catalytic) electrodes with identical geometry and area, and having analyte binding areas (biolayer) and enzyme incorporated thereto, wherein the working electrodes quantitatively measure enzymatic reaction product (see column 3, lines 12-28, column 13, lines 22-53, column 19, lines 23-45, column 15, line 63 to column 16, line 42, and column 22, lines 18-36). The unit cell may be repeated in a geometric array several hundred times on a single silicon wafer. Each working electrode is surrounded by an auxiliary (combined counter and reference) electrode. Each of the working electrodes are adjacent to permselective silane layer having immobilized thereon, the analyte binding areas which are localized on the electrode portions of the unit cell and separated from adjacent analyte binding areas by a distance (see column 25, line 35 to column 26, line 4). The working electrodes on analyte binding areas are overlain and aligned with analyte specific proteins such as antigens and antibodies (biolayer and bioactive molecules) (see column 22). Cozzette et al. specifically teach that a plurality of electrodes may be present in a biosensor for the simultaneous measurement of different analytes (see column 25 and Figure 4). The device does not include a means to mix the sample in the cell.

Response to Arguments

7. Applicant's arguments filed 2/2/04 have been fully considered but they are not persuasive.

A) Applicant argues that Henkens et al. do not anticipate the claimed invention because the reference discloses and requires a separate reference electrode for each working electrode, whereas the claimed invention uses only one common reference electrode for the plurality of working electrodes.

Contrary to Applicant's argument, Henkens et al. at column 6, lines 33-38 teach that whether in an array or a single working electrode, the biosensor may optionally include one, i.e. common, or more reference or counter electrodes.

B) Applicant argues that Henkens et al. discloses bonding the target directly to electrodes; hence, the analyte binding area is on the electrode as opposed to adjacent the electrodes.

In response, the term "adjacent" as recited in claim 1 does not exclude that the analyte binding area is attached or linked to the working electrode. Claim 1 recites, "each working electrode adjacent to one analyte binding area and *separated* from the nearest adjacent analyte binding area by a distance". Additionally, a Merriam-Webster's dictionary definition of the term defines "adjacent" as meaning 1) "having a common endpoint or border" or 2) "having the vertex and one side in common" and that the term "adjacent" is synonymous with "adjoining". Further within the definition of the term is

that "adjacent may or may not imply contact but always implies absence of anything of the same kind in between, i.e. a house with an adjacent garage.

C) Applicant argues that Henkens et al. discloses a separate well for each different electrode; hence, they are not designed to simultaneously test multiple analytes in a common solution as recited in claim 11.

In response, claim 1 does not appear to exclude that the different electrodes are in separate wells. Alternatively, Henkens et al. at column 20, lines 53-56 disclose that three electrodes are contained in a bean-shaped depression, which serves as a sample well; thus, the Henkens et al. reference reads on claim 1 as recited.

Additionally, it is noted that the feature upon which applicant relies (i.e., simultaneously test analytes in a common solution) is not recited in the rejected claims. Claim 11 appears to only recite, "all of said binding areas coated with a single quiescent solution" which does not necessarily define or limit to a "common solution".

Further in response to Applicant's argument that the electrochemical devices of Henkens is not designed to test multiple analytes simultaneously, Examiner points to column 45, lines 16-26 of Henkens et al. wherein the electrochemical devices are said to be designed to simultaneously test multiple analytes by capturing different target analytes on different analyte binding areas of the working electrodes for simultaneous detection. Hence, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

D) Applicant argues that Cozzette et al. do not disclose a common solution coating the multiple electrodes; hence, they are not designed to simultaneously test multiple analytes in a common solution as recited in claim 11.

In response, it is noted that the feature upon which applicant relies (i.e., simultaneously test analytes in a common solution) is not recited in the rejected claims. Claim 11 appears to only recite, "all of said binding areas coated with a single quiescent solution" which does not necessarily define or limit to a "common solution" and which does not exclude the teaching of Cozzette. Further in response to Applicant's argument that the electrochemical device of Cozzette cannot test multiple analytes simultaneously, Examiner points to column 25 and Figure 4 of Cozzette et al. wherein a plurality of electrodes is present in the biosensor device for the simultaneous measurement of different analytes. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

8. For reasons aforementioned, no claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:30 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
8/2/04

Gailene R. Gabel
Patent Examiner
Art Unit 16641
July 22, 2004